Remarks

Claims 1-23 and 26 are under consideration. These claims define a method of treating advanced prostate cancer by administration of an androgen suppressing amount of a LHRH agonist analog and calcitriol in an amount sufficient to enhance the effectiveness of the LHRH agonist analog. Claims 5 and 11 are amended to obviate an inadvertent typographical error.

The rejection of claims 1-4 and 16-23 under 35 U.S.C. 103(a) as unpatentable over Garnick et al. in view of Beer et al. and further in view of Lu et al. is not warranted, and is hereby traversed.

As recognized by the Examiner, neither Garnick et al. nor Lu et al. teach the administration of leuprolide together with calcitriol. Neither does Beer et al.

This secondary reference only describes the co-administration of calcitriol and docetaxel, paclitaxel and platinum compounds. Beer et al. contains no suggestion whatsoever that leuprolide or any other LHRH agonist analog should or could be substituted for docetaxel, paclitaxel or a platinum compound.

The teachings of Garnick et al. have been mischaracterized as well. To treat prostate cancer, Garnick et al. teaches the administration of LHRH-R antagonist prior to surgery. Leuprolide is not a LHRH-R antagonist, rather a LHRH-R agonist which is administered only after the treatment with a LHRH-R antagonist (Garnick et al., Examples 2 and 3). Nothing in Garnick et al. would have led one of ordinary skill, whatever that skill level may have been, to (1) ignore the express teachings of Garnick et al. vis-a-vis the use of LHRH-R antagonist and instead (2) administer calcitriol together with leuprolide.

The conclusion is inescapable that the attempted combination of Garnick et al. and Beer et al. has been arrived at only by an impermissible hindsight reconstruction of the claimed invention using applicant's own teachings as a guide.

Lu et al. does not cure the defects of Garnick et al. as a reference against the present claims. The amino acid residue sequence of Leuprolide is not an issue here.

Further, as also recognized by the Examiner, the express limitations of claims 17, 19, 21, 22 and 23 are not taught by Garnick et al. The level of ordinary skill in the

pertinent art has not been resolved in this case, thus on the present record it cannot be resolved what limitations would or would not have been obvious to one of ordinary skill. The onus is on the Examiner to make out a *prima facie* case of obviousness for the claimed invention. The Examiner has failed to do so. The rejection based on 35 U.S.C. 103(a) must be withdrawn.

The rejection of claims 1, 5-15 and 26 under 35 U.S.C. 103(a) as unpatentable over Garnick et al. in view of Beer et al., Conway et al. and Chen is unwarranted, and is traversed as well.

Garnick et al. and Beer et al. fail as references against claims 1, 5-15 and 26 for the same reasons as those advanced hereinabove. Additionally, as recognized by the Examiner, the express limitation of 1 to about 30 micrograms of calcitriol with a polysorbitan as called for in claims 6, 7, 12 and 26 also is not taught. Likewise, the express limitation of 5 to about 30 micrograms of calcitriol with a polysorbitan as called for in claims 12 and 13 is not taught.

Neither Conway et al. nor Chen cure the foregoing defects of Garnick et al. and Beer et al.

Conway et al. is clearly inapposite because it is directed to the treatment of neonatal hypocalcemia with an aqueous calcitriol solution. This has nothing to do with the presently claimed method for treating advanced prostate cancer.

Chen is also inapposite vis-a-vis the present claims. Chen teaches solubilizers for paclitaxel (col. 7, line 8) and possibly leuprolide (col. 7, line 23). These solubilizers are PEG-Vitamin Es, quaternary ammonium salts, PEG-monoacid fatty esters, PEG-glyceryl fatty esters, polysorbates; PEG-fatty alcohols (col. 7, lines 13-18; col. 14, line 67 to col. 15, line 3). Calcitriol clearly is not encompassed by the foregoing teaching, nor is calcitriol mentioned as an osteoporosis agent at col. 7, line 59, that can be solubilized using a paclitaxel solubilizer. By no stretch of imagination does Chen teach a combination of leuprolide with calcitriol or a combination of leuprolide, calcitriol and polysorbate 20, much less the presently claimed method.

The prior art compositions are clearly different, and are taught for a different purpose. Here again, as in the case of claims 1-4 and 16-23 discussed hereinabove, a

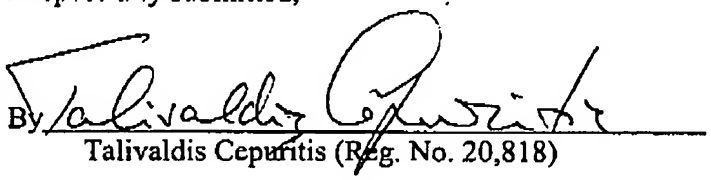
prima facie case of obviousness by one of ordinary skill in the pertinent art has not been established. Withdrawal of the rejection based on obviousness is believed to be in order.

The references cited but not applied against the claims have been reviewed with interest. Those references do not vitiate the patentability of the present claims, however.

Early passing of this application to issue is solicited.

Respectfully submitted,

November 13, 2007

By 
Talivaldis Cepuritis (Reg. No. 20,818)

OLSON & CEPURITIS, LTD.
20 North Wacker Drive
36th Floor
Chicago, Illinois 60606
(312) 580-1180

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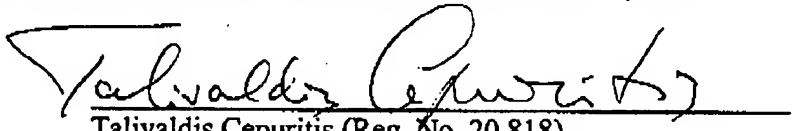
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